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09/821,879	03/30/2001	Jerry L. Kermicle	WIS4987P0081US	6744

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER  
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CHICAGO, IL 60661

EXAMINER
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FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

14

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/821,879

Applicant(s)

Kernick et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

-3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

3/31/03

- ☒ Responsive to communication(s) filed on \_\_\_\_\_.
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-72 is/are pending in the application.
- Of the above claim(s) 6-8, 18-20, 36-38, 51-58 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-5, 9-17, 21-35, 39-50, 59-72 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' amendment of 31 March 2003 has overcome the claim objections of record, the indefiniteness rejections, the rejections of claims 1-5 and 27-35 under 35 USC 112, first paragraph, the enablement rejection regarding a deposit, and the art rejections of record over Rashid et al and Nelson et al.

The application should be examined for errors. Errors appear, for example, in amended claims 25 and 32, where "claim22" and "claim29" should be replaced with --claim 22-- and --claim 29--, respectively. Errors also appear in claim 27, line 2, where "with" should be replaced with --within--.

Claims 9-17, 21-26, 39-50, and 59-68 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 4-6 of the last Office action.

Claims 9-17, 21-26, 39-50 and 59-68 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to maize plants containing the TCB trait from maize line W22-TCB (ATCC No. PTA-1601) and methods of using them, does not reasonably provide enablement for claims broadly drawn to any maize plant containing any TCB trait or gene cluster, any Tcb locus, any "modifier gene", any "pollen effect"

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gene, any "silk effect" gene, or methods of using them. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 6-8 of the last Office action.

Claims 1-5, 9-17, 21-35, 39-50, and 59-66 remain, and newly submitted claims 69-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Kermicle et al (1990), as stated on page 10 of the last Office action.

Claims 1-5, 9-17, 21-35, 39-50 and 59-68 remain, and newly submitted claims 69-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kermicle et al (1990) taken with Nelson, as stated on pages 11-12 of the last Office action.

No claim is allowed.

Applicants' arguments filed 31 March 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicants urge that the written description rejection is improper, given the description in the specification of the TCB trait, *Tcb* locus, silk effect genes, pollen effect genes, modifier genes, and their map location in relationship to molecular markers.

The Examiner maintains that Applicants have not adequately described the broad genus encompassing the multitude of claimed species. Applicants have only demonstrated the presence of a TCB gene cluster in a single population of plants derived from crossing inbred W22 with a particular teosinte accession from a particular geographic location. Applicants have not described

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any other TCB gene cluster or *Tcb* locus obtained from different populations of teosinte, or even from different crosses of teosinte and maize. Applicants attempt to describe their TCB gene cluster in terms of what it lacks, i.e. the TIC-CP1 (*Gal-m*) allele (see, e.g., page 17 of the specification, top paragraph; and page 22 of the response of 31 March 2003, penultimate paragraph). However, this definition contradicts Applicants' statement on page 17 of the specification, lines 18-22, that the W22-TCB plant which is the source of the TCB trait/gene cluster also contains the TIC-CP1 allele. Thus, Applicants have not disclosed structural characteristics which are conserved throughout their genus, and which are correlated with function.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Regarding the "silk effect" and "pollen effect" genes, Applicants state on page 16 of the specification, penultimate paragraph, that genes conferring both effects need not be present in order to constitute a TCB trait/gene cluster. Applicants provide no more guidance as to the identity of any silk effect genes or pollen effect genes, or the common characteristics of each genus.

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Furthermore, Applicants have not characterized the “modifier” genes at all, other than to say that they may be located on the same chromosome as the *Tcb* locus and linked or unlinked thereto, or else located on different chromosomes (see, e.g., page 16 of the specification, bottom paragraph).

Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Applicants urge that the scope of enablement rejection is improper, given the failure of the references cited by the Examiner to support his position, given the permissability of occasional mistakes which are later corrected, the advances in the art of assaying molecular markers, the positive conjectures by Goldman et al, and the ability of the skilled artisan to utilize molecular techniques to assay for the presence of TCB gene clusters in other maize plants.

The Examiner maintains that the cited art indeed demonstrates the unpredictability inherent in the process of identifying and characterizing genes involved in cross-incompatibility in maize. In the absence of any characterization or identification of other sources of TCB gene clusters, *Tcb* loci, pollen or silk effect or modifier genes; Applicants’ assertions that the prior art merely taught mistakes which were later corrected are not persuasive or probative. Regarding Goldman et al, the reference clearly teaches that molecular marker-mediated gene identification and characterization is quite dependent upon the choice of parents utilized as the source of the

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cross. Thus, the assignment of the TCB gene cluster on chromosome 4 at a particular location with respect to other molecular markers, based upon the crossing of W22 and a particular teosinte parent, does not provide sufficient assurance that any TCB gene cluster would be found on the same chromosome at the same location if it were derived from different parents.

Applicants' failure to actually characterize the number of loci present in the TCB gene cluster or their identity, and the vague characterization of genes conferring pollen or silk effects or modifications as stated above; further add to the unpredictability inherent in identifying other TCB gene clusters or their components from other non-exemplified sources, characterizing these gene cluster components, and incorporating them into other maize plants.

Applicants urge that the art rejections over Kermicle et al are improper, given the failure of Kermicle et al to teach a TCB trait, wherein the TIC trait taught by the reference differs from the TCB trait, particularly in terms of the presence of the TIC-CP1 locus. The Examiner maintains that Kermicle et al teach the same plants as those utilized by Applicants, i.e. crosses between W22 and a particular teosinte accession, and backcrosses to the W22 recurrent parent (see, e.g., paragraph bridging pages 22 and 23 of the specification). Furthermore, Applicants teach that the TCB gene cluster comprises a *Tcb* locus **and/or** (emphasis added) at least one modifier gene (see, e.g., page 7, lines 21-22 of the specification). Applicants also teach that the *Tcb* locus is located about 6 map units distal to the *sugary1* marker (see, e.g., page 15 of the specification, lines 17-19), which corresponds to the teachings of Kermicle et al that an incompatibility trait locus is located approximately 4 map units distal to the *sugary1* marker (see,

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e.g., page 400, Abstract). Finally, Applicants teach that the deposited W22-TCB plant indeed contains the TIC-CP1 locus (see, e.g., page 17 of the specification, bottom paragraph).

Thus, the maize plants taught by Kermicle et al appear to be the same as those claimed, even though the claimed maize plants have different names for their various loci. Thus, any method of using the claimed maize plants were also taught by Kermicle et al, who teach the same methods being applied to their plants. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Applicants' specification appears to constitute further genetic mapping of the incompatibility trait locus disclosed by Kermicle et al, wherein the authors of the prior art reference and the inventors of the instant application overlap. However, Applicants' elected invention is not drawn to a process for genetic mapping. Applicants' elected invention is drawn to products (maize plants) which appear to be the same as those disclosed by the prior art which constitutes the inventors' own work, and methods of using the plants which were also taught by the prior art. Furthermore, Applicants have not actually isolated any genes within that trait locus, or defined the number or identity of loci which constitute the TCB gene cluster, the pollen or silk effect genes, the modifier genes, or the *Tcb* locus. The imprecise and contradictory definitions of



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each component of the TCB gene cluster further hamper any attempt to distinguish it (or plants containing it) from the TIC trait taught (or plants containing it) by the prior art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 13, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

